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Request for grant of a patent

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1.	Your reference	P32127-/CMU/RTH/RMC
2.	Patent application number *(The Patent Office will fill in this part)*	0220242.2
3.	Full name, address and postcode of the or of each applicant *(underline all surnames)*	AorTech International plc Phoenix Crescent Strathclyde Business Park Bellshill Lanarkshire, ML4 3NJ
	Patents ADP number *(if you know it)*	7728249001
	If the applicant is a corporate body, give the country/state of its incorporation	United Kingdom
4.	Title of the invention	"Blood Regulation Device"
5.	Name of your agent *(if you have one)*	Murgitroyd & Company
	"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*	Scotland House 165-169 Scotland Street Glasgow G5 8PL
	Patents ADP number *(if you know it)*	1198015
6.	If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number	Country / Priority application number *(if you know it)* / Date of filing *(day / month / year)*
7.	If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application	Number of earlier application / Date of filing *(day / month / year)*
8.	Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:* *a) any applicant named in part 3 is not an inventor, or* *b) there is an inventor who is not named as an applicant, or* *c) any named applicant is a corporate body.* *See note (d))*	Yes

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Continuation sheets of this form	
Description	15
Claim(s)	
Abstract	
Drawing(s)	6

8✓

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Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*

Request for preliminary examination and search *(Patents Form 9/77)*

Request for substantive examination *(Patents Form 10/77)*

Any other documents *(please specify)*

11. I/We request the grant of a patent on the basis of this application.

Signature Murgitroyd & Company Date 02 September 2002

Murgitroyd & Company

12. Name and daytime telephone number of person to contact in the United Kingdom ROISIN MCNALLY 0141 307 8400

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"Blood Regulation Device"

The present invention relates to a conduit for connecting a first coronary compartment to a second coronary compartment such that blood can flow from the first compartment to the second compartment with a minimum of blood reflux from the second compartment back into the first compartment. In particular the conduit can connect the left ventricle of the heart to a coronary artery such that blood is able to flow from the left ventricle of the heart into the coronary artery and that reflux of blood from the coronary artery back into the left ventricle of the heart via the conduit is minimised.

Coronary artery disease is a major problem thoughout the world, particularly in Western society. Coronary arteries as well as other blood vessels can become clogged with plaque, impairing the efficiency of the heart's pumping action. This can lead to heart attacks, angina and death.

A number of methods are used to treat clogged coronary arteries such as bypass operations or balloon angioplasty.

In bypass operations one or more venous segments are inserted between the aorta and the coronary arteries to bypass the blocked portion of the coronary artery such that an unobstructed flow of blood and thus blood supply to the heart is achieved. More than 500,000 bypass procedures are performed in the US every year.

However bypass surgery is a very intrusive procedure requiring expensive and time-consuming surgery. During a bypass operation an incision is made through the patient's skin and the patient is placed on a bypass pump such that the heart can be operated on while it is not beating. A saphenous vein graft is harvested from a patient's leg and the vein is then grafted into position between the aorta and the coronary artery to allow unobstructed blood flow. This surgery is both traumatic to the patient and requires a substantial period of time in hospital and prolonged convalescence.

As indicated above, balloon angioplasty may be used to treat coronary artery plaque occlusion. In this case a deflated balloon catheter is placed within the narrowed segment of the artery and then the balloon is inflated to a high pressure, transmitting circumferential pressure and compressing the plaque.

Although this procedure is minimally invasive, this procedure can only be used in a limited number of circumstances.

In addition to the two techniques discussed above, which have been traditionally used to treat coronary artery occlusion, a more recent procedure allows a stent to be positioned between the coronary artery and the left ventricle side of the heart such that blood can flow unobstructed from the left ventricle of the heart to the coronary artery, bypassing the occluded portion of the coronary artery. The stent may be positioned between the left ventricle of the heart and the coronary artery using a less invasive procedure than that required for coronary bypass surgery.

Typically the stent is a conduit with a passage extending longitudinally therethrough. Generally a stent is cylindrical in shape.

A disadvantage of providing a stent extending from the left ventricle of the heart to the coronary artery is that blood may reflux from the coronary artery back into the left ventricle of the heart. Such refluxes of blood are undesirable.

Some reports relating to operations designed to revascularise the myocardium direct from the cavity of the left ventricle have indicated that due to the backflow of oxygenated blood back into the left ventricle chamber of the heart during diastole, the

myocardium may receive an inadequate supply of blood, leading to it becoming ischemic. Some studies have suggested that measurement of the blood flow during systole and the backflow during diastole indicates that only a 30 percent net flow rate of blood from the left ventricle chamber into the artery is achieved following introduction of a stent between the two compartments.

Strategies to overcome such reflux of blood have included providing a stent with a lining formed from a section of blood vessels, such as a vein taken from a patient. The harvesting of a vein from a patient requires invasive surgery and means that the patient is subjected to additional trauma.

However, it would be of benefit if a mechanical solution to the reflux of blood could be found which could be effected without substantially increasing the size of the stents currently provided, their cost, ease of fitting and use.

According to a first aspect of the present invention there is provided a conduit capable of extending from a first coronary compartment to a second coronary compartment the conduit enabling the passage of blood from the first compartment to the second compartment wherein the conduit comprises a valve formed from resilient material which is capable of adopting open and closed positions wherein movement of blood from the first compartment to the second compartment urges the valve towards

the open position enabling blood flow from the first compartment into the second compartment and in a closed position the valve restricts the passage of blood from the second compartment to the first compartment.

A coronary compartment is defined as any organ or any structure of the circulatory system including artery, vein, chamber of the heart or blood vessel.

At rest the conduit is ellipsoidal shape in cross-section and this shape restricts blood flow from the second coronary compartment into the first coronary compartment.

Preferably movement of blood from the first compartment to the second compartment urges the resilient material of the valve to adopt a substantially more circular cross-section thereby enabling blood to flow from the first coronary compartment into the second coronary compartment.

Alternatively the valve may comprise at least two leaflets which at rest are urged towards each other such that the passage of blood from the second compartment into the first compartment is minimised, and in this embodiment movement of blood from the first compartment to the second compartment urges the leaflets of the valve to move apart from each other enabling the passage of blood from the first compartment to the second compartment.

Preferably the conduit comprises a first end and a second end, the first end of the conduit being located at the first coronary compartment and the second end of the conduit being located at the second coronary compartment the valve being located at the second end of the conduit.

Alternatively the valve may be located at the first end of the conduit

Preferably the valve is integral to the conduit.

Preferably the first coronary compartment is a first portion of a blood vessel and the second coronary compartment is a second portion of the same blood vessel.

For example a first coronary compartment may be a first portion of an ascending venous structure such as the saphenous vein or such and the second coronary compartment is a second portion of the same ascending venous structure. If the region between the first and second portions of the femoral artery is damaged or occluded a stent may be located between the first and second portions to enable the movement of blood from the first portion to the second portion.

Alternatively the first coronary compartment is a chamber of the heart and the second coronary compartment is a blood vessel.

More preferably the first coronary compartment is the left ventricle chamber of the heart and the second coronary compartment is the coronary artery.

Thus a conduit as described by the present invention can be used to enable the movement of blood from a proximal position to a distal position in the same or different coronary compartment.

Preferably the conduit is comprised of a suitable rigid biocompatible metal including, stainless steel, spring steel and Nitinol and a flexible resilient material.

Preferably the flexible resilient material is a suitable biostable biocompatible polymer.

Preferably the flexible resilient material includes Elast-Eon™, Biomer or Biospan. .

Details of the polymer Elast-Eon™ can be found in WO98/13405, WO92/00338, WO92/09467, WO99/01496.

Preferably a plurality of conduits are longitudinally aligned to allow the flow of blood from a first conduit to a second adjacent conduit.

Preferably the conduit is collapsible such that it can be suitably placed in the body and then extended from its collapsed position to a fully extended position using a catheter.

The conduit can be placed by suitable minimally invasive techniques such as percutaneous delivery.

Alternatively the conduit is constructed of material with memory such that once suitably placed in the body it extends from a collapsed position to a fully extended position.

Preferably the conduit is two to fifteen millimetres in diameter.

An embodiment of the present invention will now be described by way of example only with reference to the accompanying figures in which;

Figure 1 is an illustration of a conduit extending from the left ventricle of the heart into the coronary artery,

Figure 2 is an enlarged view of a conduit connecting the left ventricle of the heart to the coronary artery,

Figure 3 is an illustration of a conduit wherein a second end of the conduit is in a closed position,

Figure 4 (A) is an illustration of an embodiment of the conduit in a collapsed form, (B) is am illustration of the conduit in an expanded form,

Figure 5 is an illustration of the conduit where a second end of the conduit is in an open position, and

Figure 6 is an illustration of at least two stents aligned along their longitudinal axes such that blood can flow from the lumen of a first stent to the lumen of a second adjacent stent.

As shown in figure 1 the coronary artery 10 is known to branch off the aorta 12 and be positioned along the external surface of the heart wall 14.

Following oxygenation of the blood, the oxygenated blood flows from the heart 16 into the aorta 12 and onto the rest of the body. Some of the oxygenated blood is circulated along the coronary artery 10 in order to oxygenate the muscles of the heart. In some individuals an occlusion is formed within the coronary artery due to plaque build up. These occlusions can lead to a variety of symptoms and diseases ranging from mild angina to heart attack.

In order to overcome the occlusion within the coronary artery and to restore the flow of oxygenated blood through the coronary artery it is possible to bypass the blocked portion of the coronary artery by providing a stent or a conduit 18 which extends from the left ventricle 20 of the heart into the coronary artery 10, as shown in figure 2. Location of the stent 18 as shown in

figure 2 allows blood to flow unobstructed from the left ventricle 20 of the heart to the coronary artery 10.

Overcoming occlusions of the coronary artery 10 using a stent 18 is preferable to traditional bypass surgery in that the stent 18 may be located and fitted using minimally invasive techniques. Generally the stents used to connect the left ventricle 20 of the heart to the coronary artery 10 are conduits formed by hollow tubes comprising biocompatible material such as titanium alloys, nickel alloys or biocompatible polymers. These tubes may be provided and located between the left ventricle 20 of the heart and the coronary artery 10 in a collapsed position and when suitably located extended from a collapsed position to a fully extended position using an inflatable catheter or other method.

Although such stents allow the flow of blood from the left ventricle 20 of the heart into the coronary artery, a backflow of blood from the coronary artery 10 can also occur as no means are present in the lumen of such a stent 18 to prevent the backflow of blood.

As shown in figure 3, the stent of the present invention is provided with valve means 22, one example of the valve means being a portion of flexible resilient material located at the second end 24 of the stent. This flexible resilient

material is preferably integral with the rest of the stent.

As shown in an embodiment of a stent in figure 4 the valve may be created by extension of the stent from the collapsed position.

In this embodiment, in a collapsed position, as shown in figure 4a the resilient material, held by two support elements 21, forms a cylindrical aperture 28. On extension of the stent, the resilient material may be pulled by the support elements 21 extending from the rigid biocompatible metal portion 23 of the stent 18. The pulling of the resilient material on extension of the collapsed internal metal/Nitinol structure of the stent urges the aperture formed by the resilient material to an ellipsoidal shape in cross-section. The ellipsoidal aperture restricts blood flow from the second coronary compartment into the first coronary compartment and thus the valve created is in a closed position.

It is envisaged that the stent may be located with the resilient material being urged to a closed position without the need to extend the stent structure. In addition, different methods of urging the resilient material to a closed position following extension of a stent structure from a collapsed position can be envisaged.

At rest, when blood is not being pushed from the first end 26 of the stent towards the second end of the stent 24, the flexible resilient material adopts a closed position as shown in figure 3 minimising the passage of blood from the second end 24 to the first end 26 of the stent 18. In the closed position the second end 24 of the stent 18 adopts an ellipsoidal shape such that area of the aperture 28 through which blood can flow is reduced to less than 10 percent of the area of the aperture 28 in the open position of the valve. The adoption of the ellipsoidal shape restricts the backflow of blood from the coronary artery 18 to the left ventricle 20 of the heart. Typically the reflux of blood through the valve in the closed position is less than 25 percent that which would be expected if the valve was in the open position.

During systole, contraction of the heart, the blood is pumped by the heart through the stent 18 from the first end 26 located at the left ventricle 20 of the heart towards the second end 24 of the stent located at the coronary artery. On contraction of the heart, the blood of the left ventricle of the heart is moved into the stent promoting the valve to move from an ellipsoidal shape (closed position) toward a circular shape (open position). The movement of the resilient material in this manner, from an ellipsoidal shape (closed position) toward a circular shape (open position), increases the area of the aperture 28 through which the blood can flow from the first compartment (in this case the left

ventricle of the heart) into the second compartment (the coronary artery) and allows the unobstructed flow of blood through the valve.

As the pressure of the blood flow through the valve decreases the resilient material is urged by the material and in particular embodiments the supporting elements of the rigid portion of the stent to cause the valve to adopt a resting state, wherein the aperture of the valve into the coronary artery forms an ellipsoidal shape. This change in shape of the aperture reduces the area of the aperture located at the second compartment and minimises the blood flow from the coronary artery into the left ventricle of the heart.

It can also be envisaged that at least two stents can be aligned along their longitudinal axes such that blood can be communicated from the lumen of a first stent to the lumen of a second adjacent stent. By aligning several stents together, blood may be moved from a first proximal position to a second distal position, either between two different coronary compartments such as the left ventricle of the heart and a coronary artery or within the same blood vessel such as a blood vessel.

By aligning a number of stents along their longitudinal axis it is possible to allow blood flow to be effected over a relatively large distance. In addition as each of the stents comprise valve means, the stent more closely mimics the situation in

actual veins preventing the backflow of blood and allowing blood to be moved upwards. An example of when the blood may be required to be moved upwards is in the leg of a patient when said patient is standing. The alignment of two stents along their longitudinal length such that the passages or lumens of the stents communicate with each other is shown in figure 6.

The valves present on each of the stents allow blood to be pushed through the valve on contraction of the heart, but minimise the backward movement of the blood during diastole. This allows blood to be moved up the leg and through the body.

It can be appreciated that various improvements and modifications can be made without departing from the scope of the present invention. In particular it can be envisaged that the valve means may be formed from at least two leaflets which in a resting position are urged towards each other minimising blood flow from the second coronary compartment into the first coronary compartment. However, on movement of blood from the first compartment to the second compartment, these leaflets may be pushed apart from each other, enabling blood flow from the first compartment into the second compartment. During diastole the two leaflets of the valve will be urged towards each other due to the resilience of the material, and in particular embodiments the supporting elements of the rigid portion of the stent reducing the aperture through which blood can

flow and minimising reflux of blood from the second coronary compartment into the first coronary compartment.

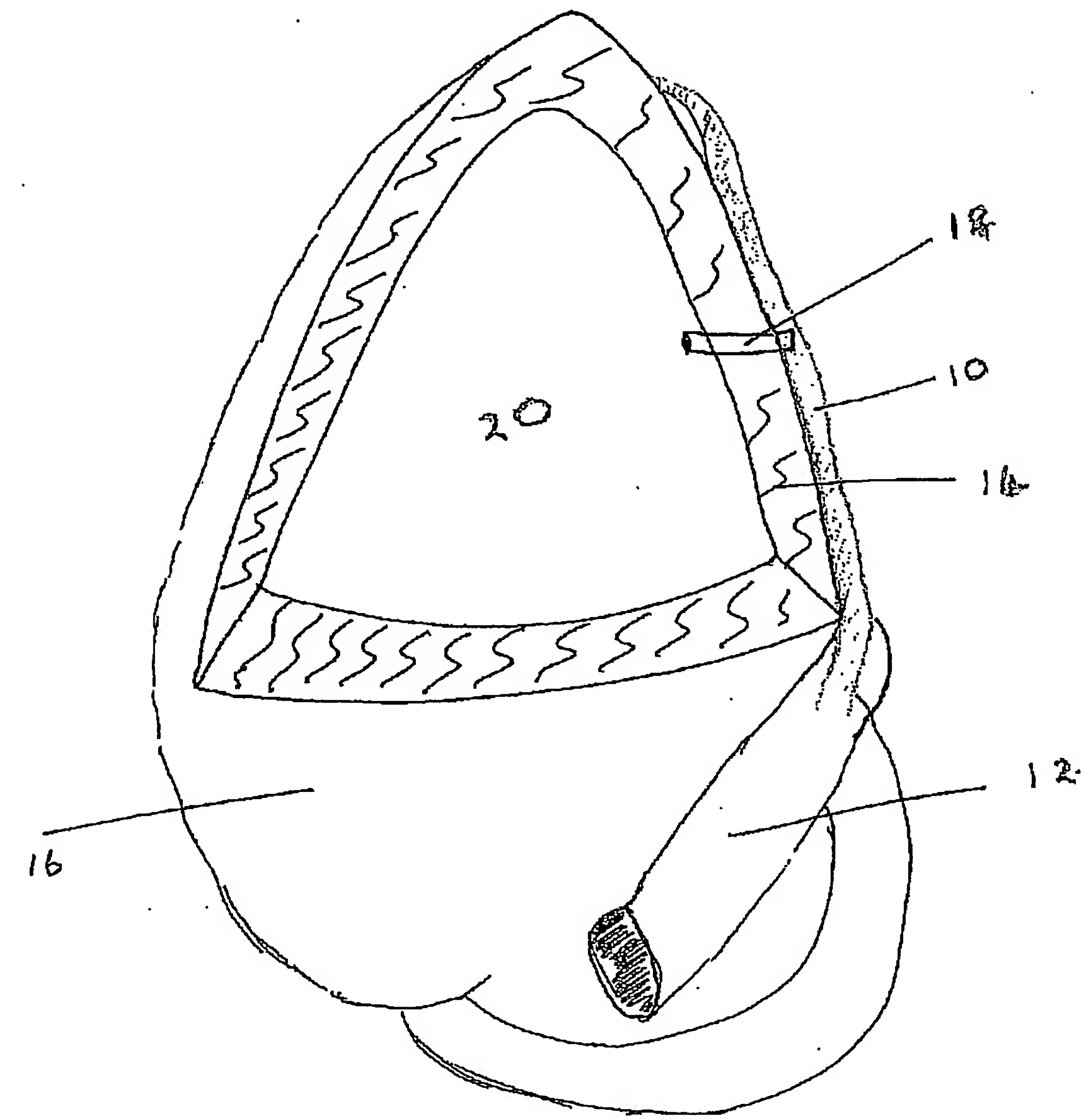


Figure 1

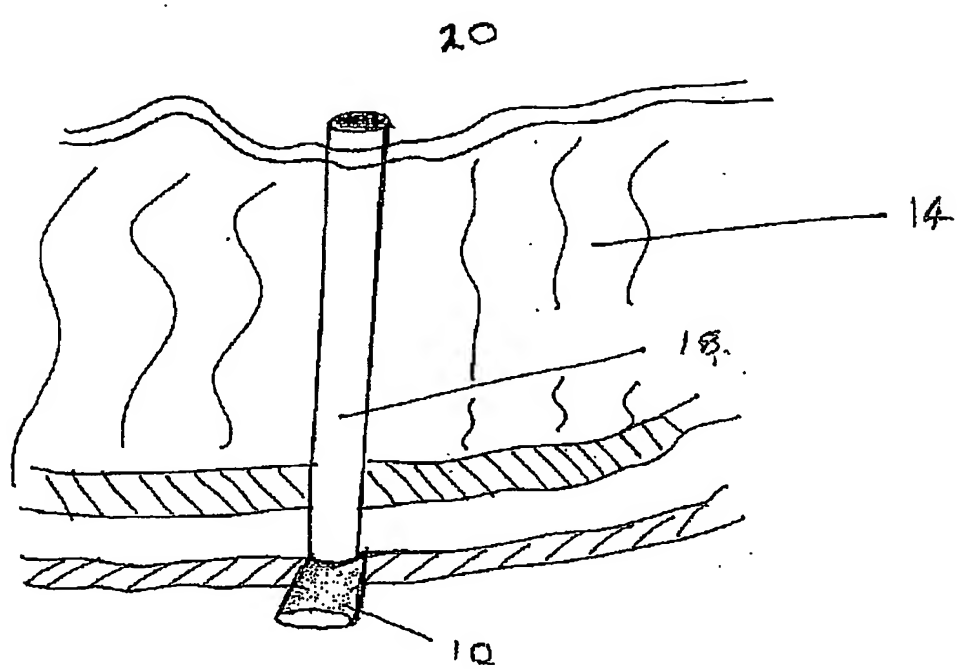


Figure 2

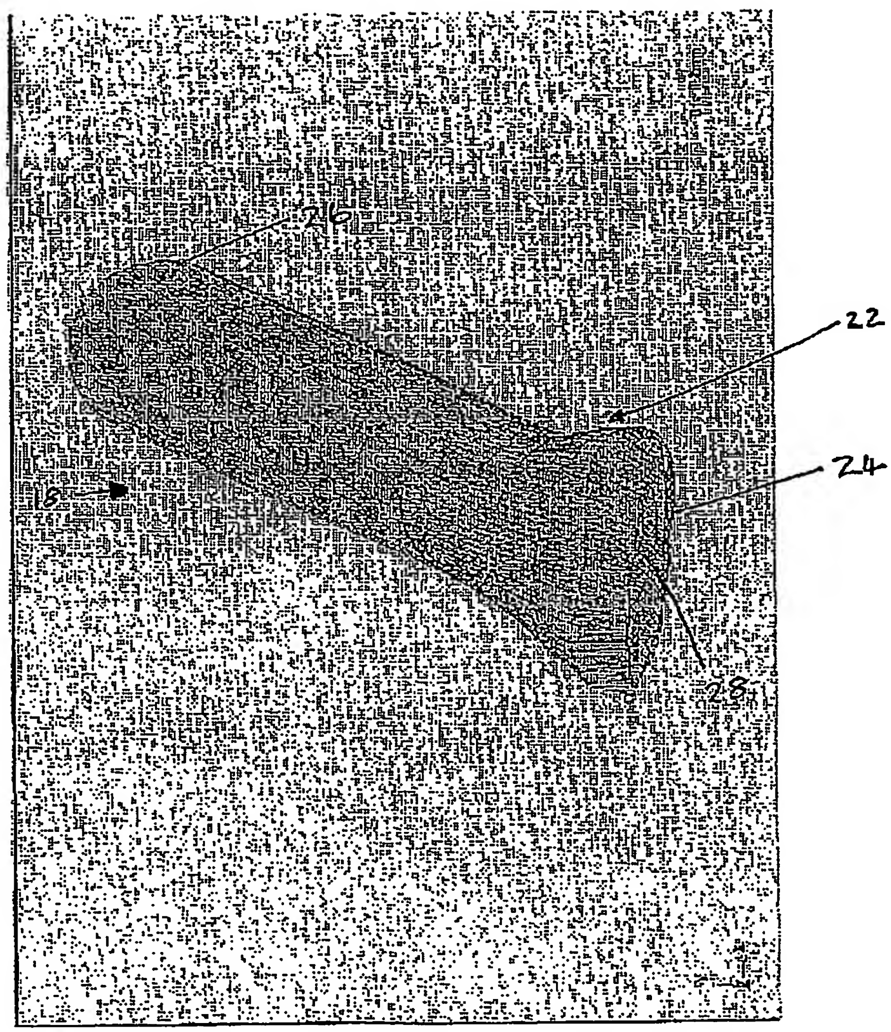
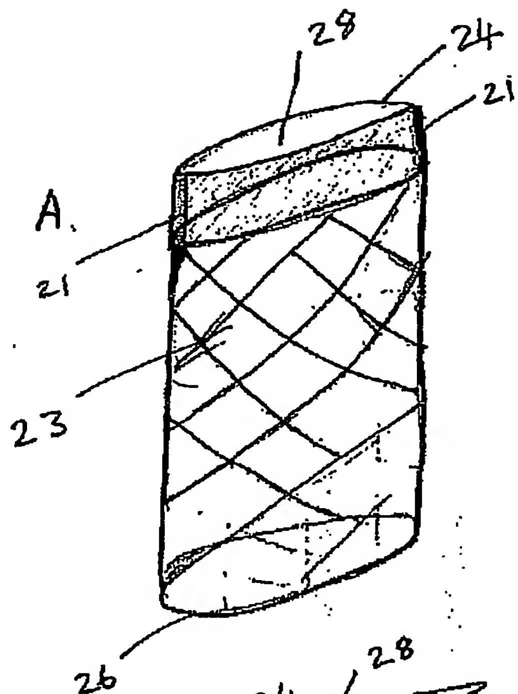


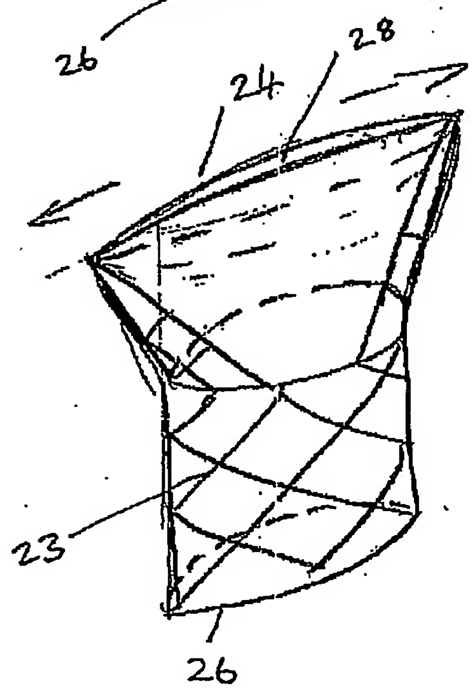
Figure 3

Figure 4

A.



B.



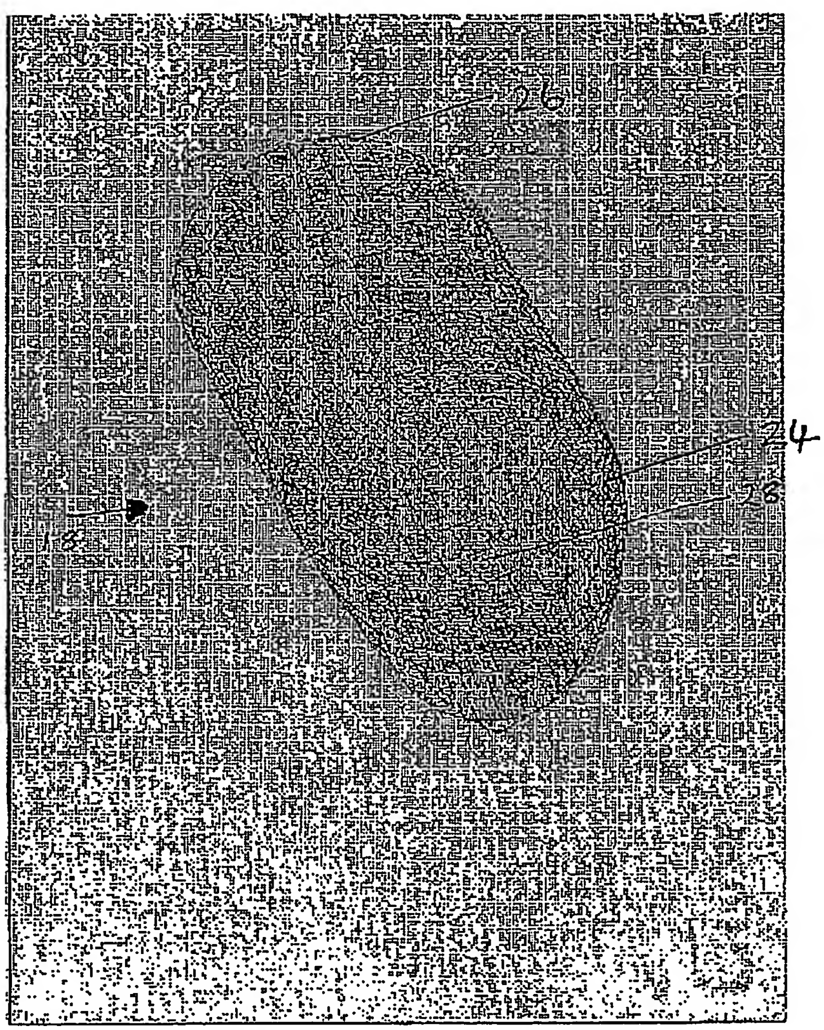


Figure 5

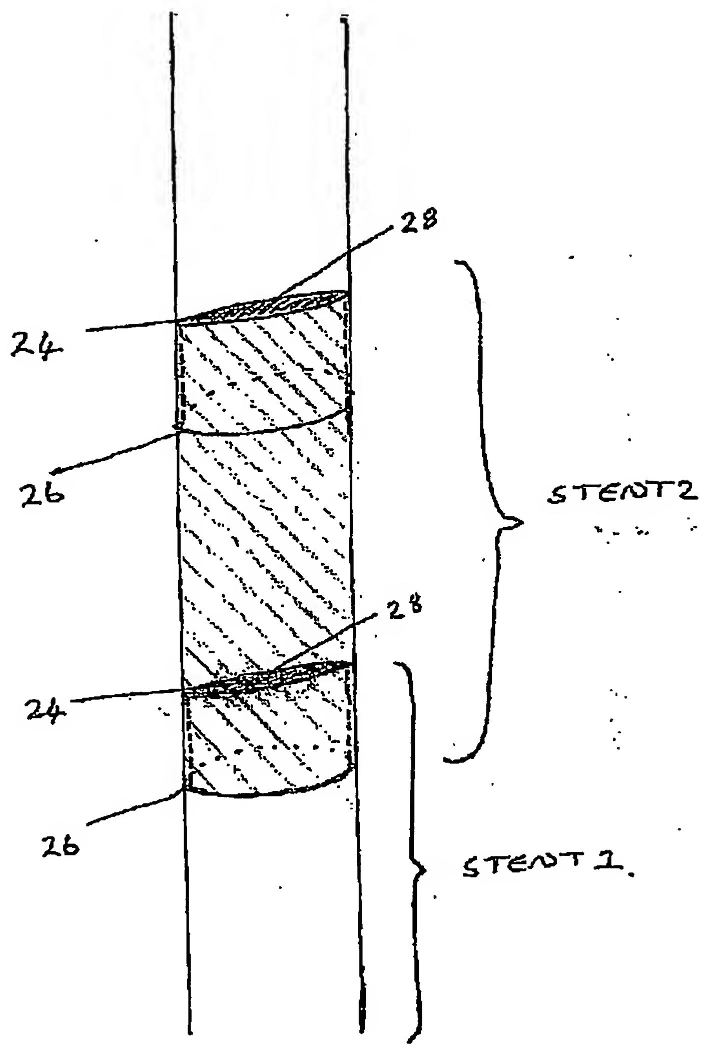


Figure 6